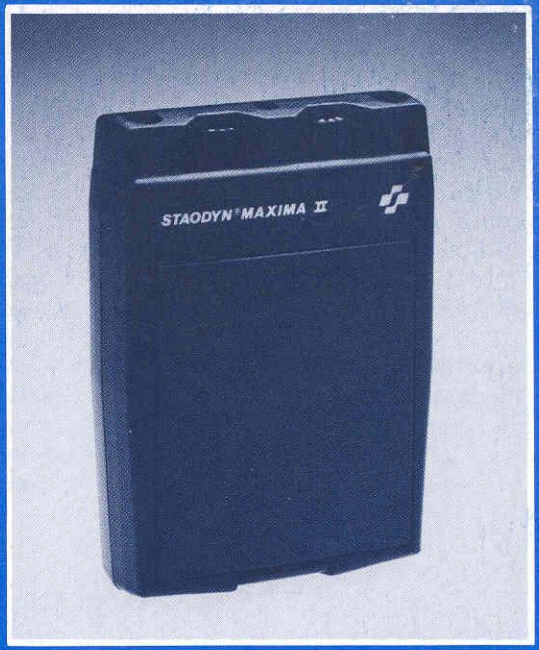
STAODYN®

Staodyn®
MAXIMA II

Transcutaneous Electrical Nerve Stimulator
(TENS)



OPERATION MANUAL

PRESCRIBING INFORMATION

Caution

Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications

Transcutaneous Electrical Nerve Stimulation (TENS) has been used successfully for many years in the symptomatic relief and management of chronic, intractable pain; and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain conditions.

Contraindications

Do not use TENS devices on patients with demand-type cardiac pacemakers.

Warnings

- Do not stimulate over carotid sinus. TENS applied over the carotid sinus or laryngeal or pharyngeal muscles may be hazardous.
- Use of TENS on individuals using certain demand-type cardiac pacemakers may be hazardous.
- TENS is not recommended for transthoracic use.
- The safety of TENS for use during pregnancy and delivery has not been established.
- TENS is a symptomatic treatment, and as such may suppress the sensation of pain that would otherwise serve as a protective mechanism on the outcome of a clinical process.
- Persistent use of TENS in the presence of skin irritation may be injurious.
- Improper use of TENS may result in electrode burns.

Precautions

- TENS devices are of no curative value.
- TENS devices should be used only under the continued supervision of a physician or under the supervision of a qualified medical practitioner to whom the patient is referred by a physician.
- TENS devices should be kept out of reach of children.
- TENS should be used with caution for undiagnosed pain syndromes until etiology has been established.
- Clinical evidence indicates that TENS is more effective for pain of peripheral origin as compared to pain of central origin.
- Treatment outcome depends on patient withdrawal from drugs and on the patient's psychological state.
- Patients with a history of skin irritation should be monitored while using TENS.
- The effectiveness of TENS is directly related to patient selection.

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INTRODUCTION

Your physician has prescribed the Staodyn® Maxima II to help relieve your pain. The Staodyn Maxima II is a Transcutaneous Electrical Nerve Stimulator, usually referred to as TENS. The Maxima II is one of the most complete TENS systems available. It has maximum capability in any of its modes of operation, yet it is remarkably simple and easy to use. This manual describes how to use and care for the Maxima II system. Read the manual carefully, and follow the directions of your physician, nurse or physical therapist. The more you understand about the Maxima II system, the more likely you are to derive the maximum benefit from its capabilities.

Pain

Pain is your body's way of telling you that you have been injured or that something is not right inside. Pain acts as a warning to remove the body from danger and compels you to seek medical attention. Once the cause of the pain has been determined, steps can be taken to correct the condition and control the pain.

Traditionally, drugs have been the pri-

mary means of controlling pain because they are simple, effective and, in most cases, safe. However, there are many patients who are less tolerant of drugs than others. These patients may experience potentially harmful side effects, such as constipation, dizziness, nausea or depressed respiration; and there may also be the risk of addiction.

What is TENS?

TENS works by delivering mild electrical signals through the skin to underlying nerve fibers to modify the perception of pain.

The TENS system consists of a small battery-powered stimulator that generates low-intensity electrical signals. These signals are passed along lead wires to two or more electrodes, which then direct the signals through the skin at the appropriate sites on the body.

Pioneering research by Drs. Melzak and Wall provided the first reasonable physiological explanation for the analgesic effect of electrical nerve stimulation. Their "Gate Control Theory," first introduced in 1965, proposed that the stimulation of primary afferent neurons closed a hypothetical "gate" mechanism at the spinal column, thereby preventing pain impulses from reaching the brain.

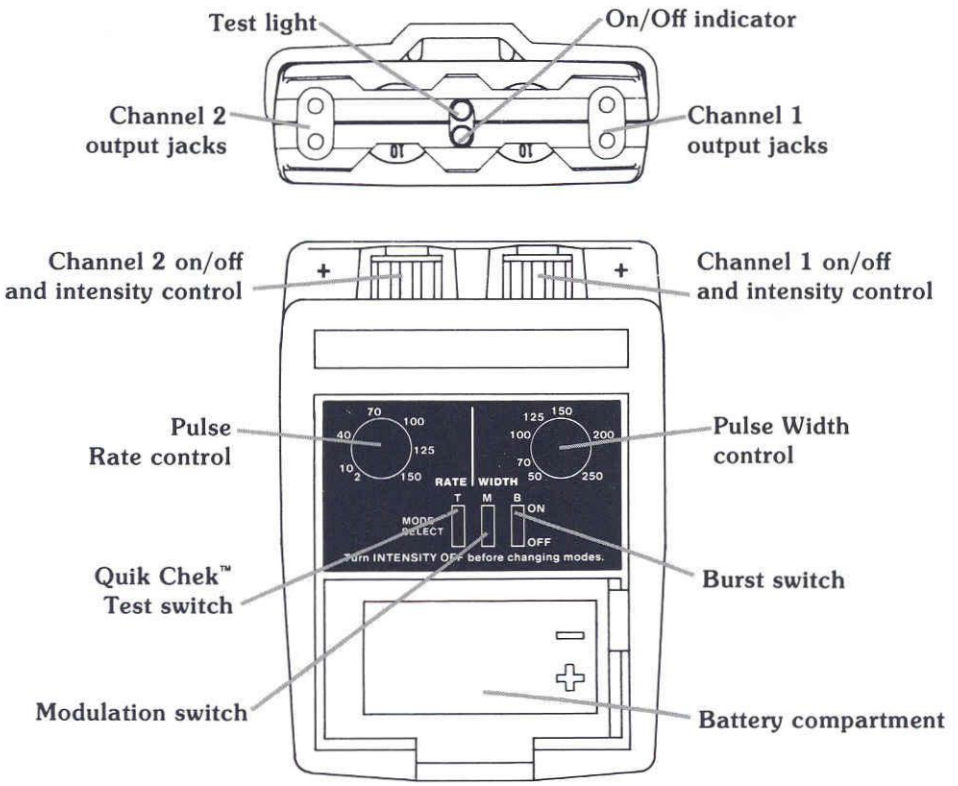
During the 1970's, after the discovery of opiate receptor sites in the brainstem, researchers unveiled a natural morphine-like peptide called an endorphin. Later developments established a possible relationship between electrical nerve stimulation and a release of endorphins within the body.

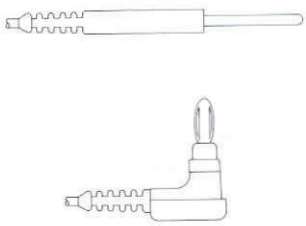
Although it is still unclear what precise neuromechanisms are involved in electrostimulation analgesia, one conclusion has remained constant: TENS is both safe and effective for many types of pain, chronic or acute, mild to severe.

Is TENS safe?

Yes. The notion of putting electricity into the body may seem frightening at first, but all you feel is a mild "tingling" sensation at the electrodes. There are no known cases of electrical shock, and unlike various drugs, TENS does not cause any potentially-dangerous side effects. Other than relieving pain, TENS does not appear to change normal perception. The only reported side effect is occasional skin irritation at the electrode sites. TENS is a symptomatic treatment only and, as such, has no curative value. Patients using demand-type cardiac pacemakers, or patients who are pregnant, may not be able to use TENS, and should consult their physician.

CONTROLS AND FUNCTIONS



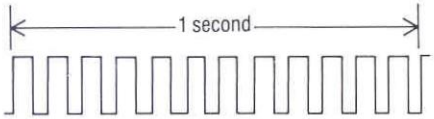


MODES OF OPERATION

The Stimulation Pulse

A variety of functions can be adjusted on the Staodyn Maxima II. The terms "rate," "width" and "intensity" describe characteristics of electrical pulses that can be adjusted by controls on the unit.

Pulse Rate (frequency): Electrical current travels in pulses of energy. Rate, or frequency, is a term that describes the number of pulses generated per second (Fig. 1) and is expressed as Hertz (Hz). The frequency range available from Maxima II is 2 to 150 Hz.

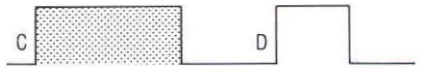


(Fig. 1)

Intensity (amplitude): In Fig. 2, the height of each pulse represents the intensity, while the area of each pulse represents the amount of energy (or charge) in the pulse. Note that pulse A is taller than pulse B. This means that pulse A has greater amplitude, and therefore more energy than pulse B. Intensity is rated in Amperes, with a milliampere (mA) being a thousandth of an Ampere. Maxima II can put out a maximum of 80 mA per channel.

(Fig. 2)

Pulse Width: Pulse width is the duration of each pulse. The energy of the pulse can be changed by adjusting the length of time current is applied during the pulse. Fig. 3 shows that pulse C has a greater electrical energy (shaded area) than pulse D because of its greater width. Pulse width is measured in microseconds (millionths of a second). Maxima II can deliver pulse widths from 50 to 250 microseconds (μs).



(Fig. 3)

Stimulation Modes

It is thought that TENS acts on the nervous system in different ways, depending on the mode in which it is being operated. The Staodyn Maxima II can be operated in a variety of modes:

Conventional (High Rate) Mode is the most frequently used mode. High Rate TENS (40 – 150 Hz) is generally preferred for long-term management of chronic pain and for controlling the dull throbbing pain associated with acute and post-operative pain.

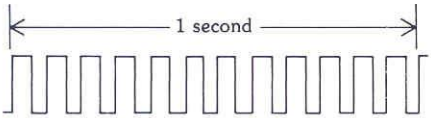
Low Rate Mode: TENS in the low rate range (2—10 Hz) is generally used as a treatment modality for short-term therapy. It is often used as an adjunct to the Conventional mode or sometimes as an alternative to the Conventional mode. In the Low Rate mode, the intensity is turned to the maximum tolerable level in order to stimulate deeper nerve fibers.

Burst Mode is a series of higher-frequency pulses delivered in bursts at a low rate (2 Hz). It is used as an alternative to the Low Rate mode. Some patients consider the Burst mode more comfortable than the Low Rate mode.

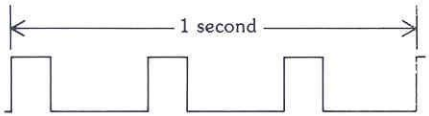
continued

In the **Modulated Mode**, the Maxima II progressively alters the pulse rate and width to produce a rhythmic, massaging sensation at the stimulation site. This mode is another alternative to the Conventional mode where longer wearing times are desired.

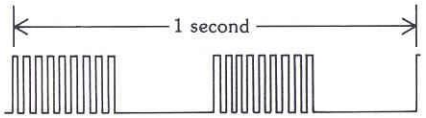
Brief-intense Mode is used primarily before or during various therapeutic procedures such as joint mobilization or suture removal. Treatment time is for short periods only and the duration of relief is very short.



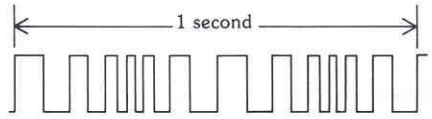
Conventional (High Rate) Mode



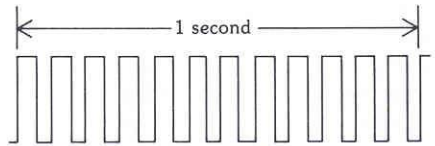
Low Rate (Acupuncture-like Mode)



Burst Mode



Modulated Mode



Brief-intense Mode

Quik Chek™ Self-Testing Feature

The most common problems associated with TENS therapy are broken leads and worn-out electrodes.

Quik Chek is a built-in feature that allows you to test your leads and electrodes to make sure they are operating correctly.

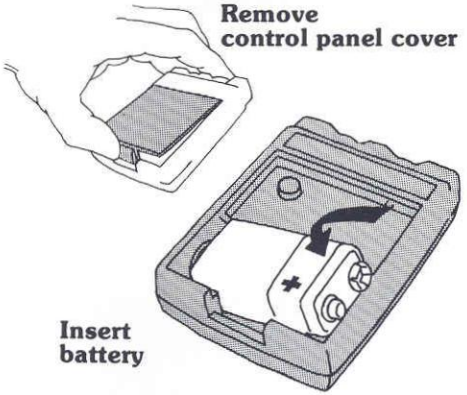
Read the "Troubleshooting Guide" section (page 14) of this manual for details about how to use the Quik Chek feature.

TREATMENT PROCEDURE

This manual assumes that your doctor, nurse or physical therapist has reviewed this or a similar device with you, determined the appropriate settings, demonstrated where and how to place the electrodes, and advised you on a treatment schedule. If you have questions or problems, check with your therapist or physician. They are familiar with your medical history and are the most appropriate sources for further guidance. Your Staodyn dealer can also be a valuable resource to understand the operation of this device.

Preparing for Treatment

1. **Insert Battery.** Remove the control panel cover and insert a 9-volt battery in the battery compartment. (Use only alkaline or nickel cadmium rechargeable batteries.) Note the polarity (+/−) of the contacts, as marked in the compartment. To check the battery, turn one of the Intensity controls ON. If the red on/off light is blinking, then the battery is "good" and the unit is functioning. Be sure to turn the unit "OFF" before proceeding with the next steps.



2. **Connect lead wires to electrodes.** Plug the pin connector into the electrode.

3. **Prepare electrodes.** A number of different types of electrodes can be used with the Staodyn Maxima II. Depending on the kind of electrode being used, either follow the directions accompanying the electrode system or refer to the appropriate instructions in the "Electrodes and Attachment" section on page 11 of this manual.

   If the electrode being used is not self-adhesive, then you will need to prepare your electrode with an adhesive patch in order to insure proper contact with the skin.

4. **Attach electrodes to the appropriate** sites on the skin. Your physician, nurse or physical therapist will determine the most appropriate electrode placement site. Continue using these locations unless otherwise instructed. Your medical team may want to try a new electrode site after a few days, or until the most effective location is determined. These sites will be recorded and you will be given a reference chart to refer to when changing electrodes at home.

   Further discussion of electrode attachment is given in the "Electrodes and Attachment" section, page 11 of this manual.

5. **Plug the lead wires into the appropriate** output jacks. In some instances, your clinician may attach significance to the polarity of your electrodes and their placement on the body. In such a case, be sure to plug the red lead into the side marked "+" (positive) on the front of

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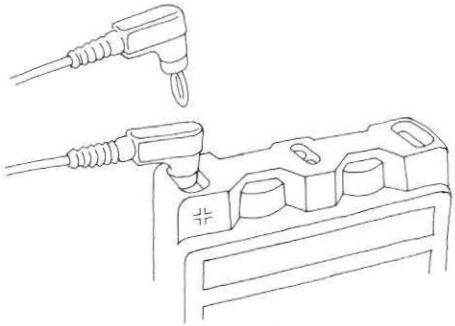
the case and the black lead into the side marked "–" (negative) on the belt clip side of the case.



You are now ready to begin your TENS treatment.

Operating Procedures

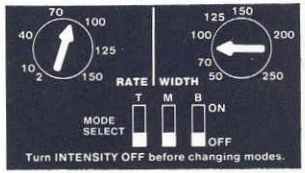
Select the mode that has been prescribed for you.

The following is a detailed description of each treatment mode, including typical settings and step-by-step procedures. The settings prescribed by your clinician take precedence over those suggested below.

Conventional (High Rate) Mode

1. **Set Controls**

Rate:	40 – 150 Hz
Width:	70 – 100 μsec
Test:	Off
Modulation:	Off
Burst:	Off



2. **Turn ON the stimulator.** Turn the Intensity control in a clockwise direction until you feel it "click" ON. The red light should begin blinking to indicate that the unit is operating. Adjust one channel at a time.

3. **Increase the intensity.** As you increase the intensity, you will begin to feel a slight "tingling" sensation under the electrodes. **Continue to increase** the intensity until you feel a slight "pulling" sensation or a slight muscle contraction. At this point, turn down the intensity to just below the level of muscle contraction. The sensation should now be strong, but not unpleasant.

   If you are using two channels, repeat this step for the other channel.

   You may wish to fine-tune the pulse rate and width. (These controls can be adjusted while the unit is turned on.)

   Pulse width: Wider pulse widths may create a sensation of "deeper" stimulation but will also deplete your battery sooner. Narrower pulse widths are generally considered more comfortable. If no noticeable benefit results from using wider or narrower pulses, use the settings recommended above.

   Pulse Rate: Higher pulse rates are often considered "smoother" but will shorten the life of the battery. Lower rate settings will significantly prolong battery life.

4. **Treatment Schedule:** When you first

begin, try to wear your Maxima II for as long as possible. Some conditions respond immediately to TENS therapy. Others require longer periods of constant stimulation before initial relief is experienced.

TENS in the Conventional mode can be worn for long periods with no ill effects. Unlike drugs, there is no dosage limitation. Use your Maxima II as you need pain relief.

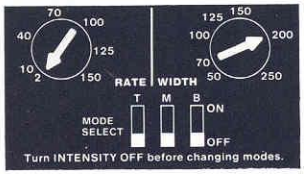
If you are likely to use your Maxima II several times during the day, leave the electrodes in place even when you are not using it. This is particularly helpful when the electrode sites are located in hard-to-reach areas of the body, such as on the back.

Electrodes should be changed regularly. The skin should be washed and allowed to breathe a little between electrode applications.

Low Rate Mode

1. **Set Controls**

Rate:	2 – 10 Hz
Width:	200 μsec
Test:	Off
Modulation:	Off
Burst:	Off



2. **Turn ON the stimulator.** Turn the Intensity control in a clockwise direction until you feel it "click" ON. The red light should begin blinking to indicate that the unit is operating. Adjust one channel at a time.

3. **Increase the intensity to maximum tolerable level.** This level is generally above muscle contraction. You will feel a strong, rhythmic pumping of the affected muscles. Try to achieve the strongest possible stimulation in order to affect the maximum number of nerve fibers.

   If you are using two channels, repeat this step for the other channel.

4. **Treatment Schedule.** Treatment with the Low Rate mode is usually given in a session lasting 15 – 30 minutes.

   Conventional mode treatment may be applied during the intervals between the Low Rate treatment sessions.

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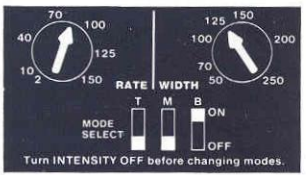
Burst Mode

1. **Set Controls**

Rate:	40 – 150 Hz
Width:	125 μsec
Test:	Off
Modulation:	Off
Burst:	On



2. **Turn ON the stimulator.** Turn the Intensity control in a clockwise direction until you feel it "click" ON. The red light should begin blinking to indicate that the unit is operating. Adjust one channel at a time.

3. **Increase the intensity to maximum tolerable level.** This level is generally above muscle contraction. You will feel a strong, rhythmic contraction of the affected muscles. The Burst mode is an alternative to the Low Rate mode. In this mode, you achieve muscle contraction by a series of intense bursts of energy rather than by the strong pulses delivered in the Low Rate mode.

   If you are using two channels,repeat this step for the other channel.

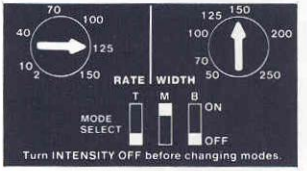
4. **Treatment schedule.** Treatment with the Burst mode is usually given in a session lasting 15 – 30 minutes.

   Conventional mode treatment can be applied during the intervals between Burst mode sessions.

Modulation Mode

1. **Set Controls**

Rate:	125 Hz
Width:	150 μsec
Test:	Off
Modulation:	On
Burst:	Off



2. **Turn ON the stimulator.** Turn the Intensity control in a clockwise direction until you feel it "click" ON. The red light should begin blinking to indicate that the unit is operating. Adjust one channel at a time.

3. **Increase the intensity.** As you increase the intensity, you will begin to feel episodes of a slight "tingling" sensation under the electrodes. **Continue to in-**

crease the intensity until the strongest sensation you feel is a slight muscle contraction. At this point, turn down the intensity to just below the level of contraction. The sensation will be a rhythmic "massaging" sensation that is strong, but not unpleasant.

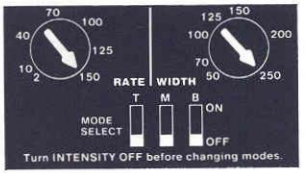
If you are using two channels, repeat this step for the other channel.

4. **Treatment schedule.** Treatment in the Modulated mode is recommended for 30 minutes to one hour. The intensity should be at the highest comfortably tolerable level below muscle contraction. The analgesic effect may last several hours after the device is turned off.

Brief-intense Mode

1. **Set Controls**

Rate:	150 Hz
Width:	250 μsec
Test:	Off
Modulation:	Off
Burst:	Off



2. **Turn ON the stimulator.** Turn the Intensity control in a clockwise direction until you feel it "click" ON. The red light should begin blinking to indicate that the unit is operating. Adjust one channel at a time.

3. **Increase the intensity to the maximum tolerable level.** These settings will produce strong muscle contraction or muscle "flickering," depending on electrode location. The sensation will be an intense "tingling" sensation that generally masks pain immediately (sometimes described as a numbing sensation at and surrounding the electrodes).

4. **Treatment schedule.** Treatment in the Brief-intense mode will usually be only for as long as the accompanying procedure lasts (i.e., joint mobilization which may last only a few minutes). Typically the Brief-intense mode is used for treatments less than 20 minutes. The analgesic effect is very short. It is usually only effective during the period of stimulation.

ELECTRODES AND ATTACHMENT

The primary link between the stimulator and the skin is the electrode. The electrode disperses the electrical current and directs it through the skin to the underlying nerves by way of a coupling medium. Secure attachment is important for effective stimulation. Some types of electrodes require adhesive patches or tape to hold the electrodes securely to the skin.

Occasional skin irritation may occur underneath the electrode or adhesive patch. For this reason, Staodyn offers a variety of electrode systems to address your particular needs.

In this section you will learn about the various Staodyn electrode systems available and the proper method of applying them.

In general, electrodes fall into two categories: disposable and reusable. Disposable electrodes are intended for single use. They are applied to the skin and left in place for a period of time, usually two or three days as specified by the manufacturer. Reusable electrodes may be applied to the skin, removed and reapplied. The number of uses depends on electrode type, skin preparation and care of the electrode between uses. Follow package instructions for specific application information.

Disposable Electrodes

Syntac™. These electrodes use a highly conductive, synthetic polymer adhesive. They are self-adhering, hypo-allergenic, have a low profile and are very flexible. They feature a breathable, tan fabric backing and are provided in a resealable foil package to assure freshness. They are available in pin or snap style connection.

Staoderm® III. These electrodes are pregelled and self-adhering. They feature a low profile, an aggressive,hypo-allergenic adhesive and provide excellent conductivity.

Reusable Electrodes

Staoderm® R. Staodyn's premium reusable electrode. These electrodes use an advanced conductive adhesive which provides excellent conductivity and allows the user to control electrode adhesion. Staoderm R's are recommended for use under conditions of **high heat** or **humidity.**

Staoderm® K. These electrodes feature karaya conductive adhesive. The electrodes are self-adhering, hypo-allergenic and gentle to sensitive skin.

Tape and Gel Electrodes

Carbon-Rubber Electrodes. Carbon-rubber electrodes are used with tape patches and Staodyn conductive gel to construct an inexpensive electrode system. A tape and gel electrode provides good conductivity and current dispersion.

Staodyn Conductive Gel. This gel is odorless, hypo-allergenic, non-staining and highly conductive. Available in 5 oz. tubes.

Staodyn Electro-grips (Tape Patches)

The adhesives used to attach electrodes are the primary source of skin irritation. However, Staodyn provides many alternatives to assure good electrode contact and minimize skin irritation.

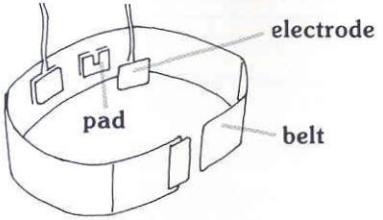
continued

SKIN CARE GUIDELINES

Lo-Tac Electro-Grips are the most popular patches. These non-woven paper patches are breathable and utilize a light, non-aggressive medical-grade adhesive.

Trans-Tac™ Electro-Grips are made of ultra-thin polyurethane material that allows the skin to breathe. They are very strong, flexible, moisture-resistant and comfortable to wear.

Hi-Tac Electro-Grips are much more aggressive in their adhesive quality. They are made of breathable material with a very tacky medical-grade adhesive.



Tapeless Electrode System. If you are sensitive to medical-grade adhesives, you may want to consider Staodyn's Tapeless Electrode System. The system uses carbon-rubber electrodes with gel that are held in place with velcro-backed pads attached to soft fabric belts.

Prevention is the key to skin care while using TENS. If you know you have sensitive skin, read all of this section. The following suggestions will help you avoid skin irritation problems:

- Thoroughly wash electrode placement area on skin, using water and mild soap before applying electrodes and each time you remove electrodes. Make sure you wash the soap off and dry the skin before you apply a protective skin preparation.
- **Always** wipe skin with a protective preparation, such as United Skin Prep™ before applying any kind of electrode. This measure alone will solve most skin irritation problems.
- Many skin problems arise from shearing stress from tape or adhesive patches that are excessively stretched across skin. To prevent this, apply tape or patches from center outward and avoid stretching over skin. Also, you want to account for flexing of skin.
- When removing tape or electrodes, always remove by pulling toward outside of body or in direction of hair growth.
- If you have very sensitive skin, wash electrode placement area well with Perri Wash™ each time you wash and each time you remove electrodes.
- It may be helpful to rub Milk of Magnesia™ (unflavored) on electrode placement area when not wearing electrodes. Milk of Magnesia™ helps return skin to neutral pH.
- Change tape and gel every 12 hours, or less, until your maximum wearing time is established. Wash carbon-rubber electrodes with mild soap and water. If you are using disposable electrodes, they may be worn up to 72 hours before changing.
- If redness develops under electrode only, try a different conductive media or electrode system.
- If irritation develops under Electro-Grip area, the patches can be trimmed. If irritation continues, try a different kind of patch or a tapeless electrode system.

TROUBLESHOOTING CHART

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
• **No stimulation felt**	• Dead battery • Battery in backward • Leads not connected correctly. • Wrong channel turned on • Broken lead wire • Insufficient gel or very dry electrode • Defective unit	• Replace with fresh battery. • Remove and insert correctly • A red and black lead should be plugged into one channel. (See "Preparing for Treatment," page 6) • Use the on/off Intensity control next to the channel connected. • Follow test procedure, page 14. • Re-gel or re-moisten, then re-apply electrodes. • Contact Staodyn dealer.
• **Intermittent stimulation** (going on and off)	• In Burst mode • Loose connection at unit or electrode • Rate too low • Broken lead wire	• Normal for Burst mode. If you don't want Burst mode, then switch "B" OFF. • Reconnect, making sure that contact is secure. • Increase rate. • Follow test procedure, page 14.
• **Not powerful enough**	• Width too narrow • Battery running low • Electrodes too dry or worn out	• Increase pulse width. • Replace battery. • Follow electrode test procedure, pages 14 and 15; re-gel or re-moisten.
• **Surges of power**	• In Modulation mode • Electrode in poor contact with skin • Defective unit	• Normal for Modulation mode. If you don't want Modulation mode, then switch "M" OFF. • Re-gel or re-moisten electrodes and re-apply. If necessary, use electro-grip or tape. Replace worn-out electrodes. • Contact Staodyn dealer.
• **Red light on top of unit is blinking**	• Normal. Stimulator is ON and is in good working order. Battery is good	• No corrective action necessary.
• **Red light on top of unit is not blinking**	• Battery is dead • Defective unit	• Replace battery. • Contact Staodyn dealer.
• **Yellow-green light on top of unit is ON**	• Test circuit is ON • Defective unit	• Unless you are testing leads or electrodes (pages 14 and 15), switch "T" off. Check for open circuit or whether unused channel may be turned ON. • Contact Staodyn dealer.

If after using this guide, the unit does not operate properly, the unit and all accessories should be returned to the Staodyn dealer you rented or purchased it from. In the event questions arise regarding any problem not covered in the Troubleshooting Guide, feel free to call the Service Department at Staodyn, Inc., (303) 772-3631, for additional information.

TROUBLESHOOTING GUIDE

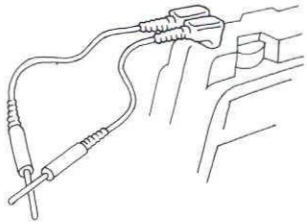
The most common problems associated with the TENS system relate to batteries, leads and electrodes.

In the event you encounter any problems with the performance of the Staodyn Maxima II, follow the steps below to identify the source of the problem.

A. **CHECK YOUR BATTERY.** When the Maxima II is ON and operating normally, the red on/off indicator light on the top of the unit will blink rhythmically. When the battery begins to run out of power, the red light will begin to dim and then stop blinking. When this happens, it is time to replace the battery. (For more information about batteries, see the BATTERIES section, page 16, of this manual.)

B. **TEST LEADS AND ELECTRODES.**
   1. **Turn unit OFF.** Be sure both channels are turned OFF. Check each channel separately.
   2. **Remove electrodes from the skin** (if they are not already).
   3. **Remove Control Panel Cover.**
   4. **Switch "T" to ON.**
   5. **Turn one channel ON** and increase until the yellow TEST light on the top of the unit comes ON. In the following tests, you will be trying to make this light go OFF.
   6. **Check leads.** Separate electrodes from the lead wires. Plug a set of lead wires into the channel you have turned on (red lead in positive (+), black lead in negative (−). With the device ON and the yellow light ON, hold the pin end of each lead together as shown in Fig. 4. **If the yellow test light remains ON,** then the leads are defective and should be replaced with a new pair. It may be necessary to wiggle and twist the leads along their length to make sure that a lead isn't making intermittent contact. (Be sure the pin ends are held together while you are twisting the leads.) **If the yellow test light goes OFF,** then the leads are in good working order and you should go on to the next step. (Repeat this step for the other pair of leads if you are using two channels.)

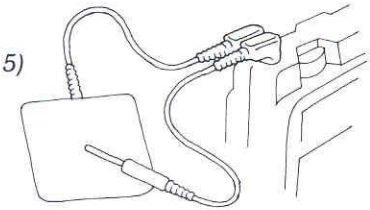
(Fig. 4)



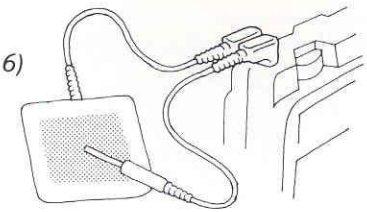
continued

7. **Check electrodes.** Eventually all electrodes will go bad and lose their ability to conduct electricity. To check electrodes, follow the steps for the type of electrode being used:
   a. **Carbon-rubber electrode.** With lead wires connected to the unit as in normal use, connect one carbon-rubber electrode to one lead. With the unit ON and the yellow light ON, take the pin end of the other lead wire and touch it to the flat side of the carbon-rubber electrode as shown in Fig. 5. **The yellow test light should go OFF,** indicating a completed circuit. Move the pin over the entire surface of the electrode while watching to see if the test light stays OFF. **If the yellow test light remains ON** (or goes ON and OFF irregularly), then the electrode is defective and should be replaced. Repeat this test for each electrode you are using.
   b. **Staoderm-K or Staoderm R electrodes.** With lead wires connected to the unit as in normal use, connect one electrode to one lead. With the unit ON and the yellow test light ON, take the pin end of the other lead wire and touch it to the conductive adhesive material within the area of the black carbon-rubber as shown in Fig. 6. **The yellow test light should** go OFF, indicating a completed circuit. Touch several other areas around the electrode, making sure the light goes OFF each time. **If the yellow test light remains** ON, then the electrode is either too dry or is defective. They must be moist in order to conduct the electrical current effectively. Try moistening the electrodes by rubbing several drops of water into the conductive material. Allow a minute or two for the water to soak in, then test the electrode again. **If the test light goes OFF now,** then the electrode was too dry. **If the test light remains ON,** then the electrode is defective and should be replaced. Repeat this test for each electrode being used.
8. If the battery, leads and electrodes all check out good, and you still feel that the unit isn't stimulating properly, then there may be a problem with the unit itself and you should contact your Staodyn dealer for assistance, or call Staodyn at (303) 772-3631.

(Fig. 5)



(Fig. 6)



BATTERIES

The Staodyn Maxima II is powered by a 9-volt battery. When the battery is "good", the red on/off indicator light will blink rhythmically. When this light stops blinking, it is time to replace the battery.

To insert a battery:

1. Be sure that both channels are turned OFF.
2. Remove the control panel cover to expose the battery compartment.
3. Hold the battery so that it matches the polarity markings (+/−) as indicated on the serial number label.
4. Push the base of the battery against the spring until there is enough clearance for the contact end of the battery to slide into place. There is no need to **force** the battery in.
5. Check that the battery is inserted correctly by turning the unit ON and confirming that the on/off light is blinking. If it is **not** blinking, then you may have put the battery in backwards, or the battery is dead. If the battery is in backwards it will not hurt the unit, but the unit will not function.
6. Replace the control panel cover.

To remove the battery:

1. Be sure that both channels are turned OFF.
2. Remove the control panel cover to expose the battery compartment.
3. Press the contact end of the battery toward the spring until the battery terminals clear the case. Then lift the battery out.

The red blinking light monitors the condition of the 9-volt battery. As the battery weakens, its voltage progressively declines. Circuitry within the unit maintains the performance of the unit down to approximately 5 volts. This means that electrical pulses and current levels will remain as adjusted over the entire rated life of an alkaline battery. As the battery voltage declines below 6 volts, the blinking light will dim. The light will turn off completely at about 4.5 volts. Below about 5 volts your Maxima II will still function normally, but you may not get the expected current levels at all intensity settings. When the battery voltage drops much below 4 volts, the unit will suddenly stop all function. How much operating time is left after the red light goes out depends on the control settings you are using. At high settings, it may only be a few minutes.

The Staodyn Maxima II will operate on a 9-volt battery, either disposable alkaline or nickel-cadmium rechargeable. Rechargeable batteries have a much shorter battery life, but can be charged hundreds of times.

We recommend use of a high-quality alkaline or nickel-cadmium battery for proper operation of your Maxima II. (Do not use the lower quality batteries commonly labeled as carbon-zinc, carbon-chloride, transistor, general purpose or heavy duty.) Alkaline batteries such as Eveready #522, Duracell MN1604A, or equivalent are recommended for disposable use. Nickel-cadmium batteries such as Eveready CH22, GE GC9 or equivalent are recommended for rechargeable use.

CARE AND MAINTENANCE

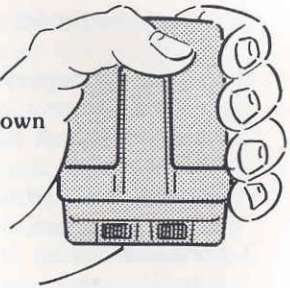
Your Staodyn® Maxima II TENS is designed to be maintenance-free. However, occasional cleaning of the stimulator is recommended. The unit and lead wires may be cleaned by wiping them with a soft cloth slightly moistened with warm water and mild soap. No other solvent should be used. Never immerse the stimulator in water.

Your Staodyn Maxima II TENS will provide years of service despite rigorous handling. However, if you are not going to be using the stimulator for a while, it is a good idea to remove the battery and store the unit in the carrying case. This will eliminate the possibility of any corrosive material leaking from the battery and damaging the unit's electrical circuitry.

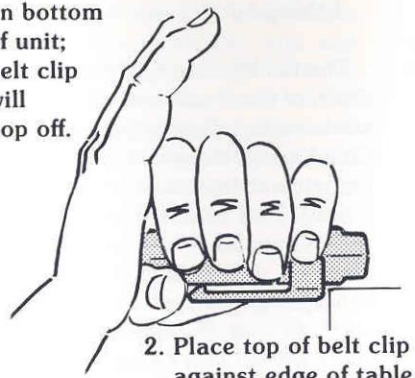
Belt Clip

Your Maxima II is equipped with a removable belt clip. To remove, use the edge of a table to press the belt clip firmly toward the bottom of the unit. (See A.) To replace, simply snap into place by pressing firmly on the belt clip. (See B.)

A.



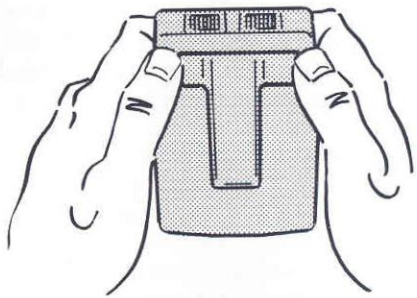
1. Firmly grasp unit in upside down position.



3. Press firmly on bottom of unit; belt clip will pop off.

2. Place top of belt clip against edge of table or counter top.

B.



To replace belt clip, press firmly at outer edges.

SPECIFICATIONS

Size: 2.58" x 3.65" x 0.86" (6.5 x 9.3 x 2.2cm)

Weight: 4.5 oz. (127g) including battery

Storage Temperature: −20°C to +50°C (−4°F to +122°F)

Operating Temperature: 0° to +50°C (+32°F to +122°F)

Waveform: Asymmetrical rectangular bi-phasic, with zero net DC current

Channels: 2 channels

Maximum current output: Each channel, 80 mA peak into 500 Ω (max. rate, max. width)

Maximum patient voltage: 75 volts (no load)

Pulse width: Max: 250 μsec
Min: 50 μsec

Pulse rate: Max: 150 Hz
Min: 2 Hz

Modulation: Width modulation decreases to 50% and increases exponentially to the pulse width setting. Modulated rate decreases to 35% of setting and increases exponentially to the rate setting.

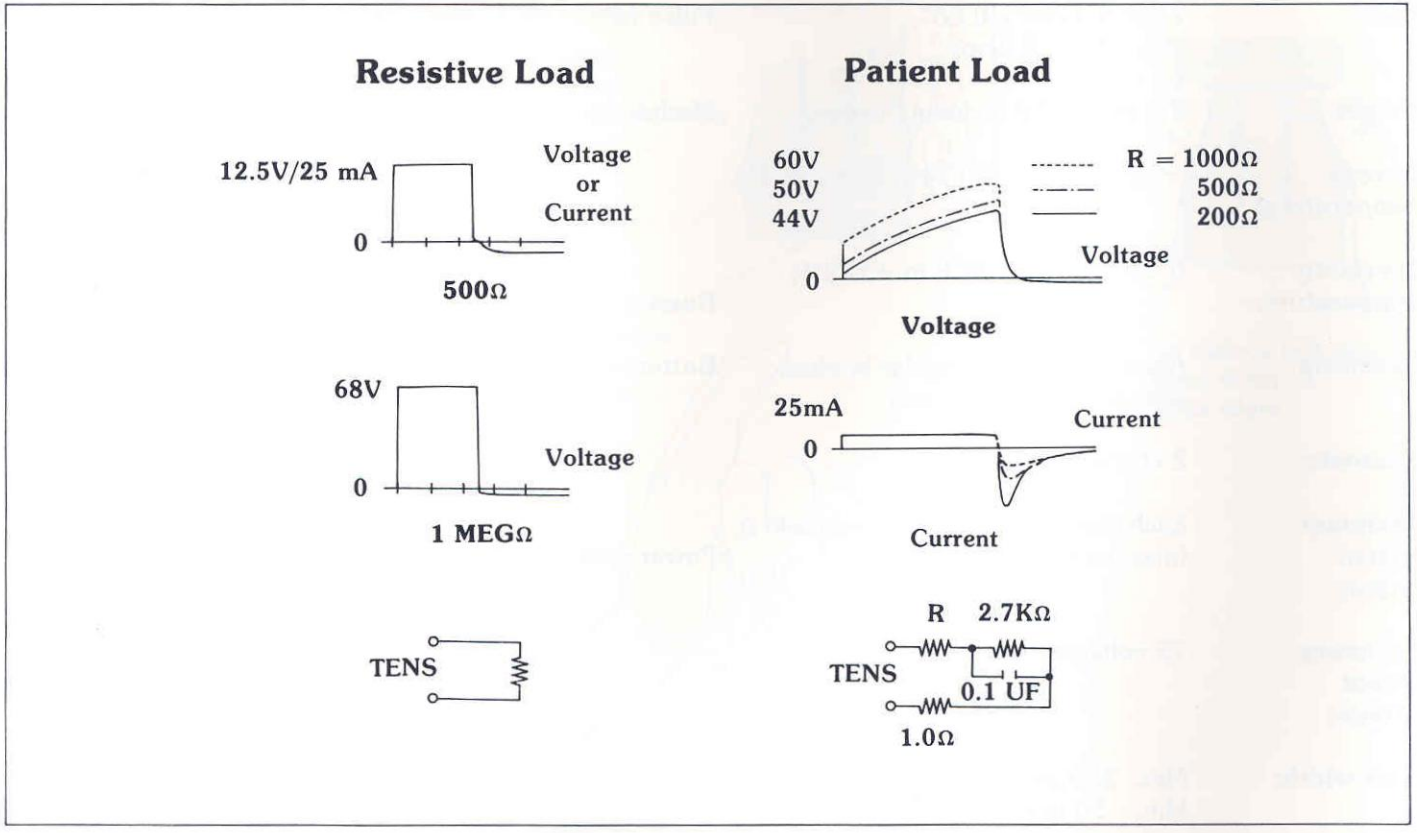
Burst: 9 pulses per burst at 2 Hz intervals

Battery Life: 25 mA in 500 Ohms, both channels continuous operation at 100 μsec width, 100 Hz rate (Intensity set to 5)
Ni-cad – 22 hours
Alkaline – 150 hours

Power source: 9-volt (alkaline or ni-cad rechargeable)

Electrical specifications nominal at 25°C. The Maxima II meets or exceeds all applicable requirements of ANSI/AAMI NS4 for transcutaneous electrical nerve stimulators.

TYPICAL OUTPUT WAVEFORMS



WARRANTY

Three-year Limited Warranty on the Staodyn® Maxima II

Staodyn, Inc., 1225 Florida Avenue, P.O. Box 1379, Longmont, CO 80502-1379 USA, warrants this unit to be free of defects in material and workmanship, for the period specified above from the date of purchase. This warranty is applicable only to the original purchaser of this unit from an authorized Staodyn dealer, or its representatives, and is non-transferable.

In the event that a component of the product is found to be defective, it shall be the buyer's responsibility to return the entire unit to the Company, at the buyer's expense.

No warranties shall apply if the unit is altered, repaired or misused by the buyer. Staodyn, Inc. can make no warranty or guarantee, express or implied, that this unit used as a medical modality will benefit any particular patient or etiology. No other warranties, express or implied, are hereby granted.

This warranty shall not apply to leads, electrodes and batteries.

Any damages arising out of shipping breakage should be brought to the immediate attention of the selling dealer.

Dear Customer,
While the above terms describe the legal limitations as well as your legal rights under our warranty, our primary concern is your complete satisfaction with our product. We would like to hear from you if you have any suggestions or complaints. Let us know how we can serve you.

W. Bayne Gibson

W. Bayne Gibson
President